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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/801,994

03/16/2004

J. Keith Joung

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EXAMINER

SHIBUYA, MARK LANCE

ART UNIT

PAPER NUMBER

1639

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/801,994	Applicant(s) JOUNG ET AL.	
	Examiner Mark L. Shibuya, Ph.D.	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 273-294, 296, 297, 299 and 300 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 273-294, 296, 297, 299 and 300 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 273-294, 296, 297, 299 and 300 are pending and examined.

Election/Restrictions

2. Claims 287-292, previously withdrawn from consideration as a result of a restriction requirement for election of species, require all the limitations of claims that appear to be free of the prior art and allowable, except for issues under 35 USC 112, second paragraph and obviousness-type double patenting, (see, below). Pursuant to the procedures set forth in MPEP § 821.04(a), **the restriction requirement among species of host cells, activation tag, polypeptide sequence, transcriptional regulatory species, DBD recognition element and reporter gene, as set forth in the Office action mailed on 10/4/2006, is hereby withdrawn** and claims 287-292 are hereby rejoined and fully examined for patentability under 37 CFR 1.104. In view of the withdrawal of the restriction requirement, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. Claims 273-294, 296, 297 are directed to a product that appears free of the prior art and allowable, except for issues under 35 USC 112, second paragraph and obviousness-type double patenting, (see, below). Pursuant to the procedures set forth in MPEP § 821.04(B), claims 299 and 300, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 10/4/2006, is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Priority

4. This application, filed 3/16/2004, states that it is a continuation of 09/858,852, filed 5/16/2001, now abandoned, which claims benefit of 60/204,509, filed 5/16/2000.

Information Disclosure Statement

5. The information disclosure statement filed 6/14/2004, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein, in regard to citations B4-B8 only, have not been considered because no copies of this are found in prior Application Serial No. **09/858,852**.

Applicant, in the Reply to the previous Office action, states that copies of B4-B8 were received in application 09/858,852, and as proven by the stamped postcard from the Office and the IDS in 09/858,852. This argument is not found persuasive, because the copies of B4-B8 are not found in the file of application 09/858,852. The stamped postcard from the Office does not state that these copies were submitted. The relevant IDS, filed 9/20/2002, in abandoned application 09/858,852, was never considered, and so does not indicate that these copies were submitted.

Specification

6. The drawings show nucleotide/amino acid sequences which must be identified by a sequence identifier, either in the drawings themselves, or in the Brief Description of the Drawings, as appropriate. The examiner respectfully requests applicant's help in identifying such sequences.

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7. The amendment to the specification, entered 4/11/2007, appears to omit commas between "23 91" in the paragraph beginning on p. 18, line 35; "15 22" in the paragraph beginning on p. 19, line 23; "95 97" in the paragraph beginning on p. 20, line 1; "95 97" in the paragraph beginning on p. 20, line 4; "95 97" in the paragraph beginning on p. 20, line 7; "95 97" in the paragraph beginning on p. 20, line 10.

8. The sequence "5'GCGTGGGCG3'" in the amendment to the specification, entered 4/11/2007, p. 5, para 4, appears to lack a sequence identifier.

Withdrawn Claim Objections/Rejections

9. The following claim objections/rejections are withdrawn in view of applicant's arguments and/or amendments to the claims:

10. Claim 279 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

11. Claims 273-286 and 293-298 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. However, the claims are rejected for being vague and indefinite over new grounds of rejection, as set forth below.

12. Claims 273-285 and 293-298 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Dove et al., 5,925,523 A**, (IDS filed 6/14/2004, cite no. A2), and in view of **Jappelli et al.**, Biochem. Biophys. Res. Commun. (1999) Vol. 266, pp. 243-247.

13. Claim 286 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Dove et al., 5,925,523 A**, (IDS filed 6/14/2004, cite no. A2), and in view of **Jappelli et al.**, Biochem. Biophys. Res. Commun. (1999) Vol. 266, pp. 243-247, as applied to claims 273-285, 293-298, above, and further in view of **Sadowski et al., US 5885779 A**.

14. Claims 273-275, 282, 293, 294, 296, 297 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over **claims 35 and 36 of U.S. Patent No. 5925523 A**, in view of **Jappelli et al.**, Biochem. Biophys. Res. Commun. (1999) Vol. 266, pp. 243-247.

Claim Rejections - 35 USC § 112, Second Paragraph

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 273-294, 296, 297, 299 and 300 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 273 recites the term "a binding site" in the penultimate line. The antecedent basis for this term is indefinite, because it is unclear that it is one of the "one or more binding sites", as stated in line 6. This indefiniteness might be overcome by the language --unique pairs of one or more of the binding sites--.

Claim 273 recites the term "a fusion protein" in the last two lines. The antecedent basis for this term is indefinite. This indefiniteness might be overcome by the language --one of the said fusion protein--.

Claim 274 recites the term "one or more binding sites" in the penultimate line. The antecedent basis for this term is indefinite, because it is unclear that it is one of the "one or more binding sites", as stated in claim 273.

Claim 280 states the language "an RNA polymerase, an RNA polymerase subunit, a functional fragment of RNA polymerase, or a functional fragment of an RNA polymerase subunit" in lines 3-4 so that it is unclear as to whether these are the same elements as in claim 277.

Claims 293 and 294 recite the limitation "a DNA binding domain" in the last line. It is unclear if this is the same as the "zinc finger DNA-binding domain" of amended claim 273.

Claim 297 recites the limitation "the polypeptide" in the last line. It is unclear if this is the same as the "the polypeptide sequence" of amended claim 296.

Claim 299 recites the limitation "a DBD recognition element" in the penultimate line. There is no antecedent basis for this limitation.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 273-275, 282, 293-298 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over **claims 1-5 of copending Application No. 10/915,233**, in view of **Jappelli et al.**, *Biochem. Biophys. Res. Commun.* (1999) Vol. 266, pp. 243-247.

Claims 1-5 of copending **Application No. 10/915,233**, are drawn to a method for detecting an interaction between a test polypeptide and a DNA sequence, comprising: i providing a population of host cells wherein each cell contains (a) a first reporter gene operably linked to a transcriptional regulatory sequence which includes one or more binding sites (DBD recognition elements) for a DNA-binding domain, (b) a second

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reporter gene operably linked to a transcriptional regulatory sequence which includes one or more binding sites (DBD recognition elements) for a DNA-binding domain, (c) a chimeric gene which encodes a fusion protein, the fusion protein including a test polypeptide, a weak DNA-binding domain and an activation tag, wherein binding of the weak DNA-binding domain of (c) to the binding sites of (a) or (b) does not cause a significant increase in the expression of the first reporter gene or the second reporter gene; wherein expression of the first reporter gene results in a first detectable signal; wherein expression of the second reporter gene results in a second detectable signal; wherein a non-specific interaction between a test polypeptide of the fusion protein and a DBD recognition element of the first and second reporter genes results in an increased level of expression of the first and second reporter genes; wherein a specific interaction between a test polypeptide of the fusion protein and a DBD recognition element of the first or second reporter gene results in a desired level of expression of either the first or second reporter gene; and ii isolating host cells comprising a fusion protein that specifically interacts with a DBD recognition element of the first or second reporter gene exhibiting a desired level of expression of the first or second reporter gene, thereby detecting an interaction between the test polypeptide and a DBD recognition element DNA sequence; and wherein the DNA-binding domain comprises zinc fingers. Thus the claims of the co-pending application are narrower in scope than the claims of the instant invention.

Claims 1-5 of copending Application No. 10/915,233, do not disclose at least 10^7 unique pairs of a DBD recognition element and a fusion protein in a population of host cells, as in claims 273-275, 282, 293, 294, 396, 297.

Jappelli et al., Biochem. Biophys. Res. Commun. (1999) Vol. 266, pp. 243-247, throughout the publication, and especially at the abstract, p. 243, para 5-p. 247, para 1, Tables 1 and 2, teach methods of identifying dimerizing polypeptides using a homodimerization system in *E. coli*, where fusion proteins libraries comprising a plurality of sequences encoding random test polypeptides were selected for the capacity to dimerize in a bacteriophage λ repressor dimerization assay, and wherein the library comprises 10^{10} members, as evidenced by ten-fold dilutions of 10^{-10} pfu/ml phage stock that produced a visible lysis of the bacterial lawn.

It would have been *prima facie* obvious at the time the invention was made for one of ordinary skill in the art to have made and used a population of host cells, each host cell comprising at least 10^{10} unique pairs of a DBD recognition element and a fusion protein are represented in the population of host cells; including libraries that contain polypeptide DBD recognition elements, and libraries that contain polypeptide sequences, as in instant claims 273-275, 282, 293-298.

One of ordinary skill in the art would have been motivated to have made and used a population of host cells, each host cell comprising at least 10^7 unique pairs of a DBD recognition element and a fusion protein are represented in the population of host cells, because Jappelli et al. at p. 247, para 1, state: "Regardless of the specific mechanism of interaction, the identification of novel sequences promoting protein

oligomerization may be important to understand the evolution of natural protein structures. In addition, it may be interesting for protein engineering applications.”

One of ordinary skill in the art would have had a reasonable expectation of success in making and using a population of host cells, each host cell comprising at least 10^7 unique pairs of a DBD recognition element and a fusion protein are represented in the population of host cells, because Jappelli et al. used such libraries to identify dimerizing polypeptides in homodimerization bacterial systems.

This is a provisional obviousness-type double patenting rejection.

Applicant, in the Reply to the previous Office action, stated that the cited claims of 10/915,233, are method claims and the examiner has not shown these claims to be patentably indistinct from the composition claims.

The examiner respectfully submits that this argument is not persuasive, because the methods and product claims of the instant application have been rejoined, (see above).

Conclusion

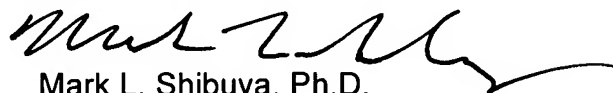
19. Claims 273-286 and 293-298 are rejected.

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20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Shibuya, Ph.D. whose telephone number is (571) 272-0806. The examiner can normally be reached on M-F, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. J. Douglas Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mark L. Shibuya, Ph.D.
Primary Examiner
Art Unit 1639